

California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Licensing Committee Report

Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
Richard Benson, Public Board Member

Report of June 15, 2005

ACTION

ACTION ITEM 1

That the Board of Pharmacy approve the proposed statutory changes to the clinic requirements.

Discussion

A board-licensed clinic is authorized to purchase dangerous drugs at wholesale and owns the dangerous drugs. This means that the authorized prescribers of the clinic can dispense from one central stock. Otherwise, each prescriber must dispense from his/her own stock of dangerous drugs and these drug stocks cannot be commingled.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The committee was provided with proposed changes to statute that would streamline the application process, better define who is accountable for the license and make license and regulatory requirements consistent between the two types of clinic licenses. The proposed changes were shared with the associations and based on comments received the language was modified. **(Attachment A)**

If the board approves the proposed statutory changes, they would be introduced in 2006 as omnibus provisions in legislation.

NO ACTION

Interim Report of the Study Conducted by UCSF School of Pharmacy and Cedars-Sinai Medical Center – Evaluation of the Impact of Pharmacists in Prevention of Medications in the Hospital Setting

At the April 2004 meeting, the Board of Pharmacy approved a waiver of CCR, title 16, sec. 1793.1(f) and 1793.7(b). The purpose of the waiver was to allow a pharmacy technician in a unit-dose drug distribution system to check another technician. The study is a sequel to the successful experimental program that evaluated technicians that concluded in December 2003.

This study is evaluating the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

The Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The study authorizes the “tech-check-tech” process to continue at CSMC, while UCSF measures the number and types of medication errors prevented during the equivalent time period that pharmacists would check the medication cassettes. The board granted the waiver for two years until April 2006.

Dr. Rita Shane from CSMC will present the interim report. **(Attachment B)**

Development of Proposal to Update the Definition of a Pharmacy, a Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists

For the December 2004 Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacists’ care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin a discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and which are part of the growing and developing independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner rather than later in anticipation of the provisions of the Medicare Modernization Act (MMA) addressing pharmacists’ services within the Medication Therapy Management Programs (MTMP) of the Medicare Act that are expected to take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists (or other health care providers) to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication “brown bag” reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

For the March 2005 Licensing Committee meeting, board counsel and staff drafted a proposal, including draft statutory changes, as a vehicle through which the committee could begin addressing the many issues. It was explained that the proposal is merely a means by which to begin the discussion. To spur discussion, the concepts were written as proposed statutory changes, but these were not presented as finished recommendations. As drafted, the proposed statutory changes update the definition of a pharmacist, and the definition of a pharmacy (to include an “intake/dispensing pharmacy,” a “prescription processing pharmacy,” an “advice/clinical care pharmacy” and a “nonresident pharmacy”) and also refine and expand the acknowledgment that pharmacy is an evolving profession that now includes more sophisticated and comprehensive patient care activities. The proposal also updates pharmacy law to more accurately reflect current pharmacy practice and the current functions of a pharmacist.

(Attachment C)

Other proposed statutory changes update the definition of a nonresident pharmacy to include entities performing prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. The proposal would require that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. The proposal would further require that only a California licensed pharmacist be able to perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

The Licensing Committee and members of the industry and the public in attendance at the meeting discussed the proposal at length. There appear to be three primary areas of philosophical debate regarding the proposal, and/or regarding the question of whether and how to regulate entities and/or pharmacists performing pharmacy services other than drug dispensing, whether inside or outside of California. During this discussion, counsel repeatedly advised that pursuant to Business and Professions Code section 4001.1 the Board of Pharmacy’s primary duty is public protection, and opined that it seemed there was little if any disagreement that the surest way to assure public protection was through licensure and control, over both in-state and out-of-state entities or individuals providing services to patients in California. The Board would need to be persuaded that the public could still be adequately protected.

1. Definition of a “pharmacy”

The proposal updates the definition of pharmacy to include a “dispensing pharmacy” that stores and dispenses dangerous drugs, a “prescription processing pharmacy” that physically processes the prescription document but doesn’t dispense dangerous drugs and an “advice/clinical center pharmacy” that provides cognitive pharmacy services such as clinical advice or information, telephonic or in-person consultation, drug utilization review, and medication therapy management but doesn’t dispense dangerous drugs.

It was expressed by some at the meeting that the definition of “pharmacy” should refer only to those entities that store and dispense dangerous drugs. These participants asserted that an entity providing related “pharmacy” services such as prescription processing and advice/clinical care

should not be licensed as a “pharmacy.” Others argued that the entities providing these services should be not be licensed at all, but if they were should be called something other than a “pharmacy.” It was also discussed that the advice/clinical care “service center” should not be required to be part of a licensed entity. Pharmacists should be allowed to perform such services as part of their California (or other state) pharmacist license.

In reviewing the laws from other states, it was observed that most states do include the related “pharmacy” services in the definition and licensure of a “pharmacy.”

It was explained that currently the board does license those entities that are only processing prescriptions as “pharmacies” and the primary reason for this is so that the pharmacy can use a pharmacy technician and/or clerk to enter the prescription into a pharmacy computer system. It was argued that licensure as a pharmacy isn’t necessary in order to use a pharmacy technician because Business and Professions Code section 4071.1 authorizes this practice, but there is not complete agreement since this section only authorizes a “pharmacy technician” to process a prescription as the agent of the prescriber.

It was also suggested that the definition of a pharmacy should be clarified to expressly exclude a physician’s office or clinic. In addition, clarification should be sought that allows a pharmacist to perform services for a physician as part of the physician’s practice, without requiring that the physician’s office be licensed as a “pharmacy.”

2. Nonresident Pharmacy

The proposal updates the definition of nonresident pharmacy to include not only those out-of-state pharmacies that dispense prescription medications to California patients, but also those that perform drug utilization review, patient consultation, medication therapy management and/or other cognitive services for California patients (or providers).

Many of these types of nonresident pharmacies are currently licensed with the board. Often times, the “call center” of a mail order pharmacy is located in one state, while the dispensing pharmacy is located in another. It was suggested that we not license the individual site but the organization that is providing the service. It was also noted that the Call Center may be required to be registered with the Telephone Medical Advice Services Bureau as required by Business and Professions Code section 4999 et.seq.

Though there was much spirited discussion on this point, as to whether non-dispensing cognitive service “sites” need to be licensed, or licensed as nonresident pharmacies, there did appear to be a rough consensus that some form of registration or licensure of these sites is appropriate.

3. California Licensure of Out-of-State Pharmacist

As part of the discussion regarding the “out-of-state call centers,” it was noted that the pharmacists providing the drug utilization review, consultation and medication management therapy (and even those pharmacists that dispense medications) to California patients are not

presently required to be licensed as California pharmacists. The proposal would require that the pharmacist providing these services be a licensed California pharmacist.

There was concern that this licensure would be burdensome to the nonresident pharmacy and out-of-state pharmacists. Various other options were discussed such as a “registration program” for the nonresident pharmacist, some type of national certification by the National Association of Boards of Pharmacy (NABP), reciprocity, no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee (see below).

The NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to patients as a “licensed pharmacist,” notify patients of the jurisdiction in which he or she is currently licensed to practice pharmacy, and register (with the respective state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction’s Board of Pharmacy address and/or telephone number.

It was explained that the current “nonresident pharmacy” model has been in place for close to 20 years and that out-of-state pharmacists are not currently required to be licensed in California if practicing within the framework of a California nonresident pharmacy. The board needs to decide if the current model is acceptable, while acknowledging that should a California patient be harmed, under the current system the board’s jurisdiction is solely over the licensed entity, and the board must rely on the state where the pharmacist is licensed to take appropriate action against the individual license (on referral).

Consistent with the requirement that pharmacists providing pharmacist care to California patients be licensed California pharmacists, the proposal would also require that the pharmacist-in-charge of a nonresident pharmacy be licensed in California. As specified above, requiring California licensure for out-of-state pharmacists-in-charge and requiring that all pharmacists providing services to California patients be affiliated with an entity with such a PIC was discussed as a possible compromise to licensing all such out-of-state pharmacists.

Pharmacist Practice in Infusion Services/Suites

The Licensing Committee was provided a copy of a letter that was jointly issued by the Department of Health Services (DHS) and Board of Pharmacy in 1997. The letter addresses whether or not a pharmacist who operates an infusion service or suite where patients receive intravenous drug therapy is exempt from licensure as a primary care clinic. Health and Safety Code section 1206(a) exempts from clinic licensure any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the scope of their license. **(Attachment D)**

It was determined that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. However, the pharmacist must comply with the protocol requirements set forth in Business and Professions Code section 4052. Since 1997, when the letter was first issued, Business and Professions Code section 4052 has changed.

DHS has requested that the Board of Pharmacy review this 1997 letter to determine if the board's interpretation is still the same and whether or not the letter should be updated. Since the letter was first issued in 1997, Business and Professions Code section 4052 has been changed, but these changes have not substantively altered the analysis. Consistent with the board's previous interpretation, under current law a pharmacist would be authorized to provide infusion services to a patient of any physician with whom the pharmacist has established a protocol.

The board will advise DHS that the board's interpretation on this issue has not changed and will update the law provisions referenced in the letter.

Meeting Summary (Attachment E)

Licensing Statistics (Attachment F)

Competency Committee Report (Attachment G)

Final Report on Committee Goals for 2004/05 (Attachment H)

ATTACHMENT A

Article 13- Nonprofit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the clinic sites owned and operated by a single county, tribe or tribal organization, non-profit corporation or public institution of higher education. A clinic that changes location, shall notify the board of the change of address on a form provided by the board.

(c) The addition or deletion of a member of the Board of Directors of a tax-exempt clinic's non-profit corporation shall be reported to the board within 30 days on a form to be furnished by the Board.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

~~—(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.~~

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing ~~least twice a year~~ quarterly that the clinic is, or is not, operating in compliance with the requirements of this article, and ~~the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.~~ Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended if appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director on a form provided by the board.

Article 14 – Surgical Clinics

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location. A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to (i) execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest, or (ii) any transfer of ownership or beneficial interest, whichever occurs earlier.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. ~~These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and clinic administrator.~~

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing least quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended in appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

ATTACHMENT B



University of California
San Francisco

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June 16, 2005

LA/OC Area Clerkship Program
Department of
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Patricia F. Harris
Executive Director
California State Board of Pharmacy
400 "R" Street, Suite 4070
Sacramento, CA 95814-6200

Re: Technician Study – Interim Report

Dear Ms. Harris:

As per the waiver approved by the Board of Pharmacy, I am submitting an interim report of the study conducted at Cedars-Sinai Medical Center: **Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting.** The attached document summarizes the results for the first 48 weeks of the study.

The results to date demonstrate that having specially-trained pharmacy technicians perform the non-discretionary task of checking technician-filled unit-dose medication carts frees up pharmacist time and enables pharmacists to play a critical role in intercepting potential medication errors and preventing harm to patients.

The study is continuing and the results will be presented to the Board upon completion. Should you need additional information about the progress of the experimental program, do not hesitate to contact me at (562) 933-0289.

Respectfully submitted,

Peter J. Ambrose, Pharm.D.
Professor of Clinical Pharmacy
School of Pharmacy
University of California, San Francisco

Enclosure

Cc: Frank Saya, Pharm.D.
Rita Shane, Pharm.D.

**Evaluation of the Impact of Pharmacists in the
Prevention of Medication Errors Associated
with Prescribing and Administration of
Medications in the Hospital Setting
Summary of Results
June 21st 2004 - May 22nd 2005**



A Collaborative Study Between
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SCHOOL OF PHARMACY



and the
Pharmacy Services Department of
CEDARS-SINAI MEDICAL CENTER

Background

- Study to determine the impact of pharmacists on prevention of medication errors during the equivalent time spent on checking medication cassettes
- 2 year study (waiver) allows technicians to check technicians filled medication cassettes
- The number and types of medication errors prevented at the prescribing step (order written by the physician) and at the administration step (medication administered by the nurse) of the medication use process will be reported

Study Objectives

- Determine top 10 drugs involved in potential prescribing and administration errors
- Determine type and frequency of medication errors intercepted at the prescribing and administration steps
- Compare intercepted errors with USP MedMARX data on errors
- Evaluate factors contributing to prescribing and medication administration errors
- Evaluate potential harm that could have resulted if error was not intercepted

Medication Related Encounters

June 21st 2004 - May 22nd 2005 (48 weeks)

Total Medication Related Encounters: **28,969 (603/week)**

- Potential Errors Intercepted (prevented): **1296**
 - Medication Prescribing : 885 (68%)
 - Medication Administration: 411 (32%)
- Other Medication Related Encounters :
 - Pharmacist dosing per MD request: 25,342
 - STAT orders: 360
 - Rounds: 58
 - Code Blue: 29
 - Drug Information: 1661

Medication Prescribing Potential Errors Intercepted

June 21st 2004 - May 22nd 2005 (48 weeks)

- Potential prescribing errors prevented by the pharmacist: 885
- Orders requiring clarification: 534 (type of error not specified)
- Types of medication ***errors intercepted which prevented****:

Wrong Dose	48.9 %	Medication Contraindicated	3.1 %
Allergy Contraindication	21.7 %	Drug Interaction	2.3 %
Necessary medications not ordered	11.7 %	Wrong Frequency/Rate	2.0 %
Duplication in therapy	5.7 %	Wrong Drug	0.6 %
Wrong Route	4.0 %		

* In those situations where error type was specified

Additionally, there were 57 incomplete orders requiring clarification.

Examples of Medication Prescribing Errors Prevented

<u>Problem Identified</u>	<u>Pharmacist Recommendation</u>	<u>Outcome Avoided</u>
Ganciclovir: 5mg/kg iv q12h pt s/p kidney transplant & renal insufficiency	Pharmacist recommended 2.5mg/kg/day for CMV induction	<i>Avoided adverse drug reaction (ADR) from overdose</i>
Oxaliplatin (chemotherapy) dosage in patient with renal insufficiency	Pharmacist recommended dosage adjustment	<i>Avoided ADR due to excessive dose of chemotherapy</i>
Celebrex ordered in patient with sulfa allergy	Pharmacist recommended alternative	<i>Avoided morbidity associated with an allergic reaction</i>
Ceftazidime ordered as 1 gm q8h for meningitis in young patient	Pharmacist recommended 2 gm q8h to achieve adequate effect	<i>Avoided sub-optimal treatment, possible mortality/morbidity</i>
Lovenox 40 mg daily ordered in patient with chronic renal failure	Pharmacist recommended change to Heparin	<i>Avoided increased risk of bleeding in patient already receiving blood transfusions</i>

Medication Administration Potential Errors Intercepted

June 21st 2004 - May 22nd 2005 (48 weeks)

Potential medication administration errors prevented by a pharmacist: 411 encounters

Types of medication *errors intercepted which prevented:*

Omission of Dose	41.2 %	Wrong Rate	5.5 %
Transcription Error	13.9 %	Wrong Drug	4.8 %
Wrong Dose	8.1 %	Drug to be given to	
Wrong Patient	6.0 %	patient was not ordered	3.8 %
Extra Dose	7.9 %	Wrong Route	3.1 %
Delay in Dose	5.7 %		

Examples of Medication Administration Errors Prevented

<u>Problem Identified</u>	<u>Pharmacist Recommendation</u>	<u>Outcome Avoided</u>
Pt. scheduled for chemotherapy in AM.	Pharmacist identified that chemo was not given	<i>Avoided omission of chemotherapy</i>
Pt was about to receive Tobramycin at a 12 hr interval; order was for q24h	Pharmacist notified nurse that dose was to be given every 24 hr	<i>Avoided potential renal (kidney) toxicity</i>
PCA pump was programmed incorrectly	Pharmacist notified nurse	<i>Avoided potential adverse events associated with excessive narcotic dose</i>
Pt receiving Potassium Chloride 60meq infusion; order was for 20meq	Pharmacist notified nurse to change infusion	<i>Avoided potential hyperkalemia and cardiac arrest</i>
Nurse transcribed Kayexalate when Kaopectate ordered	Pharmacist notified nurse about transcription error	<i>Avoided potential hypokalemia and cardiac toxicity</i>

Results compared to USP MedMARX Data

Leading types of errors include:

	USP MedMarx Data 2003 ¹	Research Study
Omission error	24 %	22.7 %
Improper dose/quantity	23 %	26.4 %
Unauthorized drug	10 %	2.1 %
Extra dose	5 %	4.2 %
Wrong patient	5 %	3.3 %
Wrong route	2 %	3.4 %

1. http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=9223078&message_id=63691&user_id=USP

TOP 10 Medications/Classes

June 21st 2004 - May 22nd 2005 (48 weeks)

Top 10 medications/classes involved in potential prescribing and administration errors

Medication Prescribing

- Chemotherapy
- Electrolytes
- Enoxaparin (Lovenox)
- Vancomycin
- Warfarin
- Levofloxacin
- Neupogen
- Fluconazole
- Cefepime
- TPN

Medication Administration

- Vancomycin
- Heparin
- Chemotherapy
- Electrolytes
- TPN
- Erythropoietin
- Warfarin
- Fluconazole
- Insulin
- Levofloxacin

Preliminary Evaluation of Potential Patient Outcomes

Pharmacist prevented medications errors associated with potential harm: 422

No Harm	340
Temporary Harm	387
Permanent Harm	11
Increase in Length of Stay	23
Death	1
Type of harm unspecified	534

Factors Contributing to Prescribing Errors

- Incomplete patient information
- Drug allergies overlooked
- Wrong drug name, dosage form or abbreviation
- Incorrect dosage calculations
- Incorrect dosage frequency
- Laboratory results not checked prior to ordering medications
- Concomitant therapy (e.g. supportive drugs for chemotherapy) necessary to prevent adverse reactions not ordered

Factors Contributing to Administration Errors

- Two patient identifiers not used
- Illegible orders
- Drug name confusion
- Incorrect pump programming
- Patients transferred and orders not transcribed accurately
- Environmental factors- distractions, interruptions and significant workload
- Staffing issues- such as shift changes and floating staff

Summary of Study Results to Date

Results of the 48 week study demonstrates the impact of pharmacists on prescribing and administration errors:

- 1296 errors intercepted by the pharmacist
- 27450 medication related encounters including dosing of medications per MD request, participation in codes, rounds and drug information questions
- Preliminary evaluation of outcomes: 422 pharmacist encounters prevented potential harm of which:
 - 387 prevented temporary harm
 - 11 prevented permanent harm
 - 23 prevented an increase in length of stay
 - 1 prevented death

REPORTS

Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes

PETER J. AMBROSE, FRANK G. SAYA, LARRY T. LOVETT, SANDY TAN,
DALE W. ADAMS, AND RITA SHANE

The rapidly changing health care environment necessitates that health care organizations optimize limited resources while improving the quality of care provided. Medication-related complications cost the American health care system as much as \$177 billion annually.¹ Pharmacist expertise in drug therapy has repeatedly demonstrated improved patient outcomes, fewer complications, and better control of the cost of medication use.²⁻⁴ However, there currently is a critical shortage of pharmacists, as documented in the Department of Health and Human Services report to Congress on the pharmacist workforce.⁵ This shortage is especially acute in California, where the ratio of 58 pharmacists to 100,000 people in the population is well below the national average of 71 pharmacists to 100,000 people in the population. In this same report, the Pharmacy Manpower Project Aggregate Demand Index for California indicated a high

Abstract: The accuracy rates of board-registered pharmacy technicians and pharmacists in checking unit dose medication cassettes in the inpatient setting at two separate institutions were examined.

Cedars-Sinai Medical Center and Long Beach Memorial Medical Center, both in Los Angeles county, petitioned the California State Board of Pharmacy to approve a waiver of the California Code of Regulations to conduct an experimental program to compare the accuracy of unit dose medication cassettes checked by pharmacists with that of cassettes checked by trained, certified pharmacy technicians. The study consisted of three parts: assessing pharmacist baseline checking accuracy (Phase I), developing a technician-training program and certifying technicians who completed the didactic and practical training (Phase II), and evaluating the accuracy of certified technicians checking unit dose medication cassettes as a daily function (Phase III).

Twenty-nine pharmacists and 41 technicians (3 of whom were pharmacy interns) participated in the study. Of the technicians, all 41 successfully completed the didactic and practical training, 39 successfully

completed the audits and became certified checkers, and 2 (including 1 of the interns) did not complete the certification audits because they were reassigned to another work area or had resigned. In Phase II, the observed accuracy rate and its lower confidence limit exceeded the predetermined minimum requirement of 99.8% for a certified checker. The mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The difference in mean accuracy rates between pharmacists (99.52%; 95% confidence interval [CI] 99.44–99.58%) and technicians (99.89%; 95% CI 99.87–99.90%) was significant ($p < 0.0001$).

Inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

Index terms: Administration; Dispensing; Drug distribution systems; Personnel, pharmacy; Pharmacists, hospital; Pharmacy, institutional, hospital; Professional competence
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level of demand for pharmacists. The current shortage of pharmacists poses a significant challenge to providing and maintaining the desired level of pharmaceutical care.⁶

The importance of pharmacy technicians in ensuring the efficient operation of hospital pharmacies is widely recognized. By reassigning nondiscretionary drug distribution tasks to pharmacy technicians, pharmacists can be redeployed to prevent adverse drug events and ensure optimal medication use. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. Pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacist shortage. Expanding the role of technicians by implementing a structured training program with ongoing quality assurance measures may ease the impact of the pharmacist shortage through the judicious and appropriate use of skilled support personnel and increase the time available to pharmacists to perform clinical functions.

Background

In 1997, the California State Board of Pharmacy was petitioned to authorize board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In response to strong opposition from some professional organizations and community pharmacists, who were concerned that the exemption could be expanded outside of the inpatient pharmacy environment and jeopardize pharmacist jobs, the board voted not to grant this petition. However, the board did express a desire to receive additional evi-

dence to further evaluate allowing pharmacy technicians to perform this function. Thus, Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) petitioned the board to grant a waiver of the California Code of Regulations to conduct an "experimental program" under the direction of the University of California, San Francisco, School of Pharmacy. The purpose of the program was to compare the accuracy of unit dose medication cassettes checked by pharmacists with those checked by trained, registered pharmacy technicians in the inpatient setting. In May 1998, the waiver was granted for the experimental program known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The waiver was initially granted through November 1, 2000, and was extended to December 2002 on the basis of data generated from this study, which was presented to the board in January 2001.

CSMC is a 900-bed, acute tertiary care hospital in Los Angeles, California, and LBMMC is a 540-bed, acute tertiary care hospital in Long Beach, California. The unit dose drug distribution system used by CSMC and LBMMC is diagrammed in Figure 1. It should be emphasized that the process of filling and checking unit dose medication cassettes is preceded by the review and verification of all medication orders by a pharmacist. The pharmacist evaluates the appropriateness of the medication, dose, dosage form, route of administration, and frequency in the order and screens for drug allergies, drug-drug interactions, and contraindications. A pharmacist is also responsible for dispensing any initial medication doses needed before the regularly scheduled unit dose cart distribution.

Pharmacy technicians do not evaluate the accuracy and appropriateness of medication orders. Pharmacy technicians perform manipula-

tive and nondiscretionary functions only under the supervision of pharmacists. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. Next, a "checker" verifies the filled cassette against the fill list to minimize the possibility of errors before the medications are sent to the nursing areas. In California, only a pharmacist can check these unit dose cassettes, which necessitated the waiver from the board of pharmacy to allow technicians to perform this function in this program. It should be noted that nurses also check the medication when removing it from a patient's cassette and confirm it with the medication administration record (also reviewed and approved by a pharmacist) before administering the medication to the patient, in accordance with Joint Commission on Accreditation of Healthcare Organizations and California Department of Health Services requirements. Thus, a medication is triple-checked before it is administered to a patient.

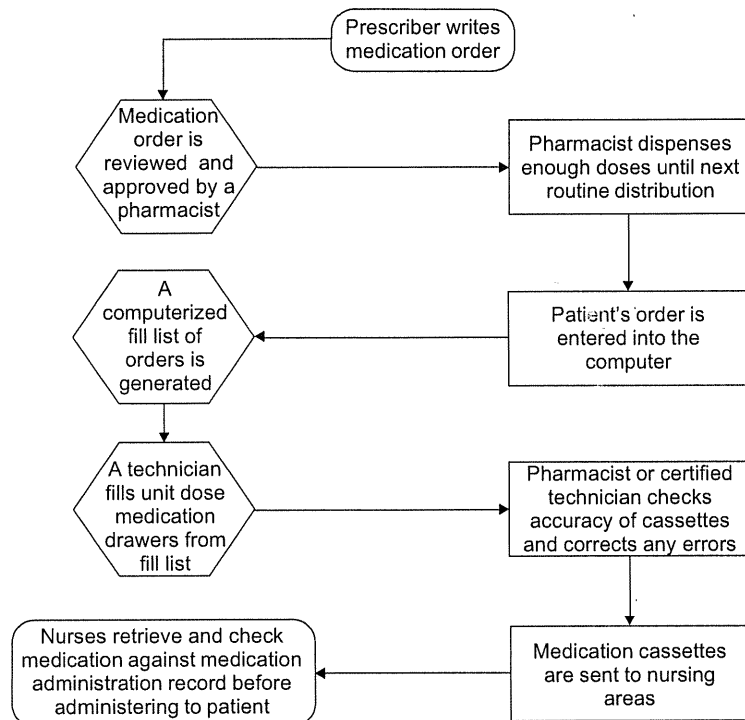
This article describes the experimental program and the accuracy of trained technicians checking unit dose medication cassettes compared with that of pharmacists.

Methods

This study was conducted concurrently at both CSMC and LBMMC and consisted of the following three phases, which were modeled from previous studies⁷⁻¹³:

- Phase I: Assessing the baseline accuracy rate of pharmacists checking unit dose medication cassettes,
- Phase II: Developing a technician training program for checking unit dose cassettes and certifying technicians who successfully completed the training program, and

Figure 1. Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study.



- Phase III: Evaluating the accuracy of certified technicians checking unit dose medication cassettes by conducting quality assurance audits.

Phase I began in June 1998 with the goal of auditing a minimum of 12,500 doses at each institution. Staff pharmacists checked all unit dose cassettes filled by technicians as was the pharmacists' normal routine during the day shift. They were aware that audits were being conducted. Study participants were selected on the basis of their normal work schedules, and no attempt was made to alter assignments. In addition to any spontaneous errors made by technicians filling the cassettes, artificial errors were randomly introduced by pharmacist "auditors" assigned to oversee the study process. Artificial errors were introduced at a rate of at least one error per 500 doses (0.2%) to coincide with a 99.8% minimum accuracy rate.⁷ The pharmacist checkers documented and corrected

any errors they detected. Subsequently, the pharmacist auditor would audit and verify the accuracy of the pharmacist checker in detecting and correcting artificial and spontaneous filling errors for all doses dispensed during the audit period. Spontaneous and artificial errors overlooked by the pharmacist checkers were documented on an audit form and corrected by the pharmacist auditors before the medication cassettes were distributed to the nursing stations. There were a total of three pharmacists at CSMC and five at LBMHC who were responsible for introducing artificial errors and auditing the pharmacists. In all three phases of the study, an error was defined as a wrong drug, dose, quantity, or dosage form; expired medication; inaccurate concentration; wrong patient's medication cassette; or missing drug.

During Phase II of the program, the pharmacy services departments at CSMC and LBMHC collaborated

on a training syllabus, qualifying examination, and data collection forms. Technicians and pharmacy interns (employed and functioning as technicians) were eligible to be included in the study if they were registered with the California State Board of Pharmacy and had at least six months of experience filling unit dose medication cassettes. They were then given didactic and practical training, in accordance with the approach used by the Minnesota Society of Hospital Pharmacists in a pilot project in which technicians were trained to check unit dose cassettes filled by other technicians.⁷ The didactic component consisted of lectures on the unit dose process, proper packaging and repackaging techniques, medication safety, and basic pharmaceutical calculations. The didactic training concluded with an examination. Technicians were required to achieve a minimum passing score of 80% on the examination. The practical training included observing a pharmacist checking unit dose cassettes and actual hands-on experience. After successful completion of the didactic and practical training, the technicians were audited for accuracy in checking unit dose cassettes for at least 3500 consecutive doses. Artificial errors, as described for Phase I of the program, were also introduced in this process. The audits were conducted by the same pharmacist auditors as in Phase I. To become a certified technician checker in this program, an overall accuracy rate of at least 99.8% was required. This phase of the study began in June 1998 and was continued as new technicians were trained and included in the program.

Phase III began in April 1999. In this phase, certified technician checkers were responsible for checking unit dose medication cassettes as a daily activity while under the supervision of a pharmacist. Monthly quality assurance audits of at least 500 doses were conducted for each certified technician checker, using

the same procedure of introducing random artificial errors as previously described. Accuracy was to be maintained at 99.8% or higher. If a certified technician checker failed a monthly audit, the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position until he or she was retrained and recertified. If a certified technician checker did not perform this function for more than three months, an audit would be conducted when the technician restarted checking medication cassettes. If a technician had not checked cassettes for more than six months, recertification was required.

In January 2000, the board approved the following requested amendment to the program: "In Phase III of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits." The amendment had been requested by CSMC and LBMMC, since no certified technician had failed a monthly audit.

Error rates were calculated as the number of errors discovered by the auditors divided by the total number of unit doses audited. The accuracy rate was defined as one minus the error rate, which was then converted to a percentage. The 95% confidence intervals for these rates and *p* values for comparing the pharmacist and technician checkers were computed using SAS, version 6.12 (SAS Institute, Cary, NC). An additional analysis was conducted to ensure that wide variation in accuracy rates among individual technicians did not exist, since this could result in a favorable mean accuracy rate and mask the performance of one or more techni-

cians who performed below the established goal of 99.8%. Mixed-effects logistic regression models with a random-checker effect were used to confirm the results.

Results

Twenty-nine pharmacists (15 at CSMC, 14 at LBMMC) participated in Phase I of the study to supply baseline data of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 working at both), three of whom were interns, participated in Phase II of the study. All 41 technicians successfully completed the didactic training, 39 successfully completed the audits and became certified checkers for Phase III, and 2 technicians (including 1 of the interns) did not complete the certification audits because they were reassigned or had resigned.

Table 1 lists the combined-institution accuracy rates of pharmacist and technician checkers in Phase I and II, respectively. For technicians, both the observed average accuracy rate and its lower confidence limit exceeded the minimum requirement of 99.8% for a certified checker. The difference in accuracy rates between pharmacists and technicians was significant ($p < 0.0001$). Interestingly, the mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The two pharmacy interns had accuracy rates of 99.89% and 99.97%. One technician had an accuracy rate of 99.75%, which was just below the target rate, and subsequently met the minimum requirement and became certified after the next audit.

In Phase III, all certified technicians at both institutions maintained a minimum accuracy of 99.8% during their monthly and quarterly audits. Phase III began in April 1999; through December 2001, no certified technician checker had failed any quality assurance audits. However, some technicians were removed from the list of certified checkers during the study period because of work reassignments or other non-study-related issues. The board of pharmacy was continually updated on the names of certified technician checkers in the semiannual reports submitted.

Discussion

The proposition of allowing trained technicians to check unit dose medication cassettes filled by other technicians has been hotly debated in California in the past decade (appendix). This study's results appear to support the ability of well-trained technicians to accurately check unit dose medications.

Several studies have been published evaluating the accuracy of pharmacy technicians in checking other technicians in a unit dose medication fill system.⁷⁻¹³ Our results corroborate the findings from these studies; in fact, we observed a higher accuracy rate for technicians than for pharmacists ($p < 0.0001$). The boards of pharmacy in Kansas, Minnesota, and Washington currently allow technicians to check unit dose medication cassettes filled by other technicians. In addition, the American Society of Health-System Pharmacists and the

Table 1.

Accuracy of Pharmacists and Technicians in Checking Unit Dose Medication Cassettes

Checker	No. Participants	No. Doses Checked	Mean Accuracy Rate(%) ^a	95% Confidence Interval (%)
Pharmacists	29	35,829	99.52	99.44–99.58
Technicians ^b	39	161,740	99.89	99.87–99.90

^aThe difference in accuracy rates between pharmacists and technicians is significant ($p < 0.0001$), using mixed-effects logistic regression models.

^bIncludes two pharmacy interns who were employed and functioning as technicians.

California Society of Health-System Pharmacists (professional policy 9801, October 1998) support the role of the technician in checking unit dose medication cassettes.

The expansion of the technician's role has been shown to increase pharmacists' productivity.¹⁴ We estimated that pharmacists at each institution spent approximately one hour per day per pharmacist checking unit dose medication cassettes before the program was implemented. In this experimental program, the pharmacists were able to use this additional time to expand clinical services and respond to drug therapy-related requests from physicians, such as dosing recommendations. The training and auditing of technicians for checking medication cassettes are centralized and carried out by the technician supervisor, who is under the direction of a pharmacist manager. By centralizing this responsibility, decentralized pharmacists gain additional time for direct patient care activities. Also, pharmacists at both institutions have reported an increase in job satisfaction after implementing the experimental program.

When evaluating the study results, some limitations should be acknowledged. The pharmacist checkers selected to determine the baseline accuracy rate of checking unit dose medication cassettes were those who happened to be staffing the inpatient areas on the dates that the audits were performed. Neither the pharmacist checkers nor the dates of the audits were randomized. The pharmacists and the technicians were

cognizant of the study, although they did not necessarily know when audits were to be conducted. Artificial errors introduced were not randomized using a random numbers table but were based on the judgment of the pharmacist auditors who attempted to introduce a variety of different errors. The auditors at each institution introduced errors independently. In addition, the severity of errors was not defined in the study; therefore, this information was not included in the results.

The results of this study were presented to the California State Board of Pharmacy, which is now reconsidering allowing technicians to check unit dose cassettes filled by other technicians in the inpatient setting, under the same conditions of this study. The waiver for this study expires in December 2002. Until state regulations are changed or the expiration date is reached, both institutions will continue to gather data from the quarterly audits.

Conclusion

In this study, we concluded that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

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Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians

Year	State Regulation
Before 1993	Acute care hospitals in California were permitted to allow technicians to check the accuracy of technician-filled inpatient unit dose medication cassettes, under chart order exemption in the pharmacy regulations.
1993	The use of inpatient pharmacy technicians to check technicians filling unit dose cassettes was deemed unacceptable by the California State Board of Pharmacy, as evidenced by the following correspondence provided to the California Association of Hospital and Health Systems: "Please note the law does not authorize a technician to check another technician. While a technician may check another technician, the final check must always be done by a pharmacist."

Continued on next page

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians *(continued)*

<u>Year</u>	<u>State Regulation</u>
1994	The Hospital Pharmacy Committee of the California State Board of Pharmacy proposed draft language to add a section to the California Code of Regulation (CCR1717) to allow pharmacy technicians to check the work of other pharmacy technicians in connection with filling unit dose medication cassettes for patients whose orders had been previously reviewed by a pharmacist.
1995	This draft language was presented in May at a board of pharmacy informational hearing.
1996	<p>In June, as a result of failure to reach agreement over the proposed language, the board developed a technician committee. This committee was charged to evaluate the entire pharmacy technician program including changes necessary to improve the program, discuss and plan for future changes and roles of technicians, and pursue any statute or regulatory changes necessary to accommodate these practices.</p> <p>The committee, in an October report to the board, recommended several potential changes including asking the board to consider allowing technicians to check the work of other technicians for unit dose medication cassette filling under a waiver system that included specific provisions (e.g., functions). In response to this report, the board of pharmacy voted to move forward with regulatory action to allow technicians to check the accuracy of technicians' work in a unit dose medication cassette fill system. During this time, the board of pharmacy began to enforce the California Code of Regulations relating to the use of technicians for checking of unit dose medication cassettes and required facilities to discontinue the practice.</p>
1997	<p>In May, responding to requests from multiple health systems and the California Society of Health-System Pharmacists, the board of pharmacy gave notice of its intent to amend regulations to allow technician checking of technician-filled unit dose medication cassettes.</p> <p>All interested parties were provided an opportunity to provide oral testimony at the proposal hearing in July. At that time, the board of pharmacy did not approve moving forward with the amended regulations. In response to the many delays in reaching consensus to change current regulations, representatives from LBMMC and CSMC developed the proposal in collaboration with the University of California, San Francisco, School of Pharmacy to perform a study in order to provide the board with objective data.</p>
1998	On May 27, the board granted the requested waiver of the California Code of Regulations to conduct the "experimental program." The waiver was initially granted until November 1, 2000. However, the waiver was subsequently extended until February 1, 2001.
2001	In January, having reviewed the results of this study, the board extended the waiver until December 2002.

ATTACHMENT C

Proposed Scope of Practice Revisions – Licensing Committee March 16, 2005

§ 4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of a valid, unexpired pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded.~~ The profession of pharmacy may be practiced in diverse settings, including the following:

(1) "Intake/dispensing pharmacy" means an area, place, or premises licensed by the board in which "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail by personnel licensed by the board.

(2) "Prescription processing pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(3) "Advice/clinical center pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(4) "Nonresident pharmacy" means an area, place, or premises licensed by the board that is located outside this state, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. It may be any or all of types (a)(1) to (a)(3).

(b) These pharmacy types are not mutually exclusive.

(c) Unless otherwise specified, whenever the term “pharmacy” is used in this chapter, it shall be deemed to refer to every one of the types in (a)(1) to (a)(4). Unless otherwise specified, each requirement made applicable to any pharmacy by this chapter is applicable to all.

~~(b)~~(d) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(e) “Pharmacy” shall not include any of those clinics listed in Section 4180 or Section 4190.

§ 4050. Professional status

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

- (1) Interpreting, verifying, and implementing drug orders and prescriptions;
- (2) Dispensing pursuant to legitimate drug orders and prescriptions;
- (3) Ensuring proper drug storage, documentation, labeling and record-keeping;
- (4) Maintaining accurate, complete, and confidential patient profiles and records;
- (5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
- (6) Designing and implementing quality assurance procedures and protocols;
- (7) Compounding drug products pursuant to prescription and for prescriber office use;
- (8) Maintaining safe, secure, and sanitary conditions in licensed premises;
- (9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
- (10) Collaborating with prescribers and other care providers regarding patient care;
- (11) Implementing standardized procedures and protocols regarding patient care;
- (12) Administering or furnishing drugs or biologicals where permitted by law;
- (13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
- (14) Such other pharmacy functions as are authorized by this chapter.

(ab) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture~~, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(bd) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.-

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication-drug product~~ to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) ~~Perform the following procedures or functions in a licensed health care facility as authorized by Section 4052.1. in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)(A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2. in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)(A) Furnish emergency contraception drug therapy in accordance with either of the following as authorized by Section 4052.3.:

(9) Administer immunizations under the supervision of a prescriber.

(i) ~~Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

(ii) ~~Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

(B) ~~Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~

~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

~~(be) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.~~

~~(cd) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.~~

(de) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1. Performance of procedures or functions in a licensed health care facility; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2. Performance of procedures or functions authorized by other providers; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services,

the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.41. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4110. Licenses; renewal; transfer; temporary permits; fees

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(ef) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter.

(fh) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(gi) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(hj) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(jk) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; designation; responsibilities; notifications

(a) Every pharmacy shall designate a pharmacist-in-charge, and shall not operate as a pharmacy without a designated pharmacist-in-charge. and w~~Without 30 days thereof of a new or replacement designation, the pharmacy shall notify-submit an application for approval of this designation to the board stating in writing of the identity and license number of that the designated pharmacist-in-charge, pharmacist and the date he or she was designated. The designated pharmacist-in-charge must have a valid, unexpired pharmacist license issued by the board. Where a designated pharmacist-in-charge has been denied a license, had a license revoked, suspended, or placed on probation, or is the subject of an ongoing board investigation into possible unprofessional conduct, the board may prospectively refuse or retroactively withdraw its approval of the designation and require that the pharmacy designate another pharmacist-in-charge.~~

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge. This duty is separate from and additional to that stated in subpart (a).

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(ed) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(de) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4122. Consumer information; posting or written receipts; prices

(a) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies. The format and wording of the notice shall be adopted by the board by regulation. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy.

(b) A pharmacist, or a pharmacist's employee, shall give the current retail price for any drug sold at the pharmacy upon request from a consumer, however that request is communicated to the pharmacist or employee.

(c) If a requester requests price information on more than five prescription drugs and does not have valid prescriptions for all of the drugs for which price information is requested, a pharmacist may require the requester to meet any or all of the following requirements:

(1) The request shall be in writing.

(2) The pharmacist shall respond to the written request within a reasonable period of time. A reasonable period of time is deemed to be 10 days, or the time period stated in the written request, whichever is later.

(3) A pharmacy may charge a reasonable fee for each price quotation, as long as the requester is informed that there will be a fee charged.

(4) No pharmacy shall be required to respond to more than three requests as described in this subdivision from any one person or entity in a six-month period.

(d) This section shall not apply to a nonresident pharmacy, or to a pharmacy that is located in a licensed hospital and that is accessible only to hospital medical staff and personnel.

(e) Notwithstanding any other provision of this section, no pharmacy shall be required to do any of the following:

(1) Provide the price of any controlled substance in response to a telephone request.

(2) Respond to a request from a competitor.

(3) Respond to a request from an out-of-state requester.

§ 4125. Quality assurance program

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors and/or inappropriate provision of cognitive services such as prescription review, consultation, drug utilization review, or medication therapy management attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(b) As used in this section, and subject to subdivision (e), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(e) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(ij) For licenses referred to in subdivisions (fg), (gh), and (hi), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

(1)-a Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) -Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

ATTACHMENT D

STATE OF CALIFORNIA--HEALTH AND WELFARE AGENCY

DEPARTMENT OF HEALTH SERVICES

Licensing and Certification
1800 Third Street, Suite 210
P.O. Box 942732
Sacramento, CA 94234-7320
(916) 445-3054

Carol W.



March 28, 1997

To: All California Licensed Pharmacists

Subject: Infusion Services/Suites

The California Department of Health Services (DHS) and the California State Board of Pharmacy (BOP) wish to clarify an issue that relates to the practice of pharmacy, the operation of a licensed clinic, and the operation of infusion services and infusion suites.

The BOP licenses pharmacists and pharmacies in California. The DHS, Licensing and Certification Program, licenses health facilities and clinics. Recently enacted changes in the pharmacy law, Business and Professions Code Section 4027 and 4052 [4046], have resulted in questions and some confusion among pharmacists in California.

The question of concern is whether a pharmacist, who contracts with a health care service plan and operates an infusion service or suite where patients receive intravenous drug therapy, is exempt from licensing as a primary care clinic.

Health and Safety Code Section 1206(a) exempts from clinic licensure requirements any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the scope of their license.

The BOP has concluded that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. Such pharmacists must comply with all the requirements set forth in Sections 4052(a)(5)(A) and 4052(b) [4046(c)(5)(A)] of the Business and Professions Code as it relates to pharmacists' services in a health care service plan.

Pharmacists operating infusion services or suites which do not comply with these requirements would potentially be in violation of Section 1205 of the Health and Safety Code. This law requires that all clinics be licensed by DHS.

Questions concerning the practice of pharmacy should be addressed to the BOP at 400 R Street, Suite 4070, Sacramento, CA 95814.

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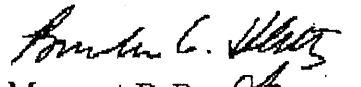
All California Licensed Pharmacists

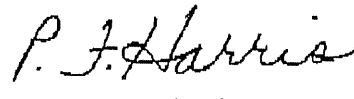
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March 28, 1997

Questions concerning the operation of a clinic under the Health and Safety Code should be addressed to William Murray, Pharm.D., Chief Pharmaceutical Consultant, Department of Health Services, Licensing and Certification, P.O. Box 942732, Sacramento, CA. 94234-7320.

Note: Sections of the Business and Professions Code shown in brackets [] are from California Pharmacy Law 1995. Unbracketed section numbers are from Pharmacy Law revised January 1, 1997.


Margaret DeBow
Deputy Director
Licensing and Certification


Patricia F. Harris
Executive Officer
State Board of Pharmacy

cc: BOP Supervising Inspectors

John Hagerty, Chief
L&C Field Operations Branch

ATTACHMENT E



California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE

Meeting Summary

DATE: June 15, 2005

TIME: 9:30 a.m. – 3:00 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
Richard Benson, Public Member

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector
Anne Sodergren, Manager
Jan Perez, Legislative Coordinator
Joshua Room, Deputy Attorney General

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Proposed Statutory Changes to the Licensure and Regulation of Clinics

Licensing Unit Manager Anne Sodergren reported that at the last Licensing Committee meeting, the committee was provided with proposed changes to the licensing requirements for clinics. Because of comments that were received, the proposal was tabled for further discussion with the interested parties. Based on these discussions, the proposal was revised accordingly.

Ms. Sodergren explained that a board-licensed clinic is authorized to purchase dangerous drugs at wholesale and owns the dangerous drugs. This means that the authorized prescribers of the clinic can dispense from one central stock. Otherwise, each prescriber

must dispense from his/her own stock of dangerous drugs and these drug stocks cannot be commingled.

Consistent with the board's Strategic Plan objective to review all licensing programs, board staff reviewed the board's licensing requirements for clinics. During the review several inconsistencies between the requirements for nonprofit or free clinics and surgical clinics were noted.

The committee was provided with proposed changes to statute that would streamline the application process, better define who is accountable for the license and make license and regulatory requirements consistent between the two types of clinic licenses. Other than some minor clarification of the language, no other comments have been received.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed statutory changes to the clinic requirements. The statutory changes would be introduced in 2006 as omnibus provisions.

Pharmacist Self-Assessment Mechanism (PSAM)

The National Association of Boards of Pharmacy (NABP) announced in May 2005 the availability of the PSAM. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on NABP's web site at www.nabp.net.

The PSAM, which is applicable to general pharmacy practitioners in all practice settings, consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour but a maximum of 3 hours per section is allowed. Pharmacists may take all three sections in one sitting, or complete one section at a time, but once a section is begun, it must be completed in its entirety. All three sections must be completed within 30 days of beginning the first section. The fee for the PSAM is \$75.

The PSAM does not report scores to any person or group other than the testing pharmacist. Once the pharmacist has completed the mechanism, he or she will receive a confidential achievement report indicating the percentage of questions answered correctly in each of the five content areas as well as the overall percentage of questions answered correctly. The achievement report is separate from the record of completion and has no identifiers of the test taker.

It was noted that the Idaho State Board of Pharmacy will award pharmacists 4 hours of continuing education to complete the assessment. The Licensing Committee directed that staff determine if other states also award continuing education for the PSAM or any other pharmacist self-assessment mechanism for professional development and to report back to the committee with its findings. Also, it was suggested that the California Pharmacy Education Foundation or perhaps ACPE may accredit self-assessment mechanisms as another option for pharmacists to obtain continuing education credit.

Accreditation Council for Pharmacy Education (ACPE) No Longer Recognizes Drug and Device Manufacturers as ACPE Accredited CE Providers

The Licensing Committee was provided with an announcement from ACPE that it will no longer recognize drug and device manufacturers as ACPE accredited continuing education providers. This will become effective July 1, 2005.

Infusion Services/Suites

The Licensing Committee was provided a copy of a letter that was jointly issued by the Department of Health Services (DHS) and Board of Pharmacy in 1997. The letter addresses whether or not a pharmacist who operates an infusion service or suite where patients receive intravenous drug therapy is exempt from licensure as a primary care clinic. Health and Safety Code section 1206(a) exempts from clinic licensure any place or establishment owned or leased and operated as a clinic or an office by one or more licensed health care practitioners for the practice of their profession within the scope of their license.

It was determined that a pharmacist who operates an infusion suite or service and who contracts to provide these services to patients of a health care service plan is functioning under the scope of his or her license as a pharmacist. However, the pharmacist must comply with the protocol requirements set forth in Business and Professions Code section 4052. Since 1997, when the letter was first issued, Business and Professions Code section 4052 was changed.

DHS has requested that the Board of Pharmacy review this 1997 letter to determine if the board's interpretation is still the same and whether or not the letter should be updated. Since the letter was first issued in 1997, Business and Professions Code section 4052 has been changed, but these changes have not substantively altered the analysis. Consistent with the board's previous interpretation, under current law a pharmacist would be authorized to provide infusion services to a patient of any physician with whom the pharmacist has established a protocol.

Ms. Harris stated that she would advise DHS that the board's interpretation on this issue has not changed and will update the law provisions referenced in the letter.

Competency Committee Report

Pharmacist Licensure Examination

Assistant Executive Officer Virginia Herold reported that the board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since this time, the board has received 3,580 applications to take the California license exams; 1,605 individuals have become licensed as pharmacists since mid-June and 2,692 individuals have been made eligible to take the licensure examinations; 2,028 individuals have been verified to the NABP as qualified to take the NAPLEX for California (includes score transfers); 2,268 CPJE examinations have been administered and 488 have failed the CPJE examinations. Also, 96 regrades of the CPJE have been performed (resulting in no change in score). The CPJE's current pass rate is 81.5 percent.

Restructure of the Competency Committee

Ms. Herold reported that President Goldenberg has appointed 8 new members to the Competency Committee. She anticipates that with these new appointments, the board will be able to move forward in restructuring the committee as approved by the Board of Pharmacy last year. It will be a two-tier structure – a core committee and a group of item writers. The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination. She added that the board is continuing its efforts to recruit pharmacists to participate as members of the committee.

Job Analysis

Ms. Herold explained that the board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline. The board completed its last job analysis in 1999/00.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses will be tallied by the board's examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

Administration of the CPJE – New Vendor Contract

Ms. Herold reported that the board's CPJE is administered through Experior Assessments, LLC, at test centers statewide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because each agency is not required to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years.

At this time, the tentative RFP release date is July 5th. Review of the responses to the RFP by the evaluation team will be completed by September 20th. The new contract should be awarded by October 7th, leaving four months to implement a transition to the new contract before the end of the current contract (which can be automatically extended to February 2006).

Delays in this process could impact the ability of applicants to take the CPJE after February 2006. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems.

Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients

For the December 2004 Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacists' care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin a discussion on how the board should address these many issues that do not fit the traditional statutory definition of pharmacy and which are part of the growing and developing independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings. However, the committee was encouraged to develop a proposal sooner rather than later in anticipation of the provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act that are expected to take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists (or other health care providers) to provide MTM for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

For the March 2005 Licensing Committee meeting, board counsel and staff drafted a proposal, including draft statutory changes, as a vehicle through which the committee could begin addressing the many issues. It was explained that the proposal is merely a means by which to begin the discussion. To spur discussion, the concepts were written as proposed statutory changes, but these were not presented as finished recommendations. As drafted, the proposed statutory changes update the definition of a pharmacist, and the definition of a pharmacy (to include an "intake/dispensing pharmacy," a "prescription processing pharmacy," an "advice/clinical care pharmacy" and a "nonresident pharmacy") and also refine and expand the acknowledgment that pharmacy is an evolving profession that now includes more sophisticated and comprehensive patient care activities.

The proposal also updates pharmacy law to more accurately reflect current pharmacy practice and the current functions of a pharmacist. It also requires that a pharmacist who performs cognitive services for California patients be licensed in California. Additionally, it specifies that

a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Statutory changes are also proposed to the pharmacist scope of practice sections (Bus. & Prof. Code, § 4052), which are technical clean up to make the statutes easier to read and understand. These sections provide for pharmacists' collaborative practice with a physician pursuant to a protocol. There is no substantive change to the scope of practice for pharmacists, the protocol requirements, or the emergency contraception drug therapy requirements.

Other proposed statutory changes update the definition of a nonresident pharmacy to include entities performing prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. The proposal would require that the pharmacist-in-charge of a nonresident pharmacy be a California licensed pharmacist. The proposal would further require that only a California licensed pharmacist be able to perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

In addition, to the proposal would require a pharmacy to include in its quality assurance program not only the documentation of medication errors, but also documentation of inappropriate provision of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management. The board is also given authority to investigate matters related to the performance or provision of cognitive services. It is proposed that the definition of unprofessional conduct for a pharmacist be amended to include those acts or omissions that involve the failure to exercise or implement a pharmacist's best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services, and also those acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct would further be amended to include acts or omissions that involve the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

The committee and members of the industry and the public in attendance at the meeting discussed the proposal at length. There appear to be three primary areas of philosophical debate regarding the proposal, and/or regarding the question of whether and how to regulate entities and/or pharmacists performing pharmacy services other than drug dispensing, whether inside or outside of California. During this discussion, counsel repeatedly advised that pursuant to Business and Professions Code section 4001.1 the Board of Pharmacy's primary duty is public protection, and opined that it seemed there was little if any disagreement that the surest way to assure public protection was through licensure and control, over both in-state and out-of-state entities or individuals providing services to patients in California. The Board would need to be persuaded that the public could still be adequately protected.

1. Definition of a “pharmacy”

The proposal updates the definition of pharmacy to include a “dispensing pharmacy” that stores and dispenses dangerous drugs, a “prescription processing pharmacy” that physically processes the prescription document but doesn’t dispense dangerous drugs and an “advice/clinical center pharmacy” that provides cognitive pharmacy services such as clinical advice or information, telephonic or in-person consultation, drug utilization review, and medication therapy management but doesn’t dispense dangerous drugs.

It was expressed by some at the meeting that the definition of “pharmacy” should refer only to those entities that store and dispense dangerous drugs. These participants asserted that an entity providing related “pharmacy” services such as prescription processing and advice/clinical care should not be licensed as a “pharmacy.” Others argued that the entities providing these services should be not be licensed at all, but if they were should be called something other than a “pharmacy.” It was also discussed that the advice/clinical care “service center” should not be required to be part of a licensed entity. Pharmacists should be allowed to perform such services as part of their California (or other state) pharmacist license.

In reviewing the laws from other states, it was observed that most states do include the related “pharmacy” services in the definition and licensure of a “pharmacy.”

It was explained that currently the board does license those entities that are only processing prescriptions as “pharmacies” and the primary reason for this is so that the pharmacy can use a pharmacy technician and/or clerk to enter the prescription into a pharmacy computer system. It was argued that licensure as a pharmacy isn’t necessary in order to use a pharmacy technician because Business and Professions Code section 4071.1 authorizes this practice, but there is not complete agreement since this section only authorizes a “pharmacy technician” to process a prescription as the agent of the prescriber.

It was also suggested that the definition of a pharmacy should be clarified to expressly exclude a physician’s office or clinic. In addition, clarification should be sought that allows a pharmacist to perform services for a physician as part of the physician’s practice, without requiring that the physician’s office be licensed as a “pharmacy.”

2. Nonresident Pharmacy

The proposal updates the definition of nonresident pharmacy to include not only those out-of-state pharmacies that dispense prescription medications to California patients, but also those that perform drug utilization review, patient consultation, medication therapy management and/or other cognitive services for California patients (or providers).

Many of these types of nonresident pharmacies are currently licensed with the board. Often times, the “call center” of a mail order pharmacy is located in one state, while the dispensing pharmacy is located in another. It was suggested that we not license the individual site but the organization that is providing the service. It was also noted that the Call Center may be required

to be registered with the Telephone Medical Advice Services Bureau as required by Business and Professions Code section 4999 et.seq.

Though there was much spirited discussion on this point, as to whether non-dispensing cognitive service “sites” need to be licensed, or licensed as nonresident pharmacies, there did appear to be a rough consensus that some form of registration or licensure of these sites is appropriate.

3. California Licensure of Out-of-State Pharmacist

As part of the discussion regarding the “out-of-state call centers,” it was noted that the pharmacists providing the drug utilization review, consultation and medication management therapy (and even those pharmacists that dispense medications) to California patients are not presently required to be licensed as California pharmacists. The proposal would require that the pharmacist providing these services be a licensed California pharmacist.

There was concern that this licensure would be burdensome to the nonresident pharmacy and out-of-state pharmacists. Various other options were discussed such as a “registration program” for the nonresident pharmacist, some type of national certification by the National Association of Boards of Pharmacy (NABP), reciprocity, no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee (see below).

The NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to patients as a “licensed pharmacist,” notify patients of the jurisdiction in which he or she is currently licensed to practice pharmacy, and register (with the respective state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction’s Board of Pharmacy address and/or telephone number.

It was explained that the current “nonresident pharmacy” model has been in place for close to 20 years and that out-of-state pharmacists are not currently required to be licensed in California if practicing within the framework of a California nonresident pharmacy. The board needs to decide if the current model is acceptable, while acknowledging that should a California patient be harmed, under the current system the board’s jurisdiction is solely over the licensed entity, and the board must rely on the state where the pharmacist is licensed to take appropriate action against the individual license (on referral).

Consistent with the requirement that pharmacists providing pharmacist care to California patients be licensed California pharmacists, the proposal would also require that the pharmacist-in-charge of a nonresident pharmacy be licensed in California. As specified above, requiring California licensure for out-of-state pharmacists-in-charge and requiring that all pharmacists providing services to California patients be affiliated with an entity with such a PIC was discussed as a possible compromise to licensing all such out-of-state pharmacists.

Committee Chair Conroy thanked the participants and encouraged them to submit any suggested proposals on the policy issues and proposals discussed in writing for consideration at the next meeting in September. She added that it is important that barriers are not erected that would impact good pharmacist care for California patients, while balancing and understanding the board's fundamental role of public protection.

Adjournment

Licensing Committee Chair Ruth Conroy adjourned the meeting at 3:00 p.m.

ATTACHMENT F

APPLICATIONS		FYTD 2002/03	FYTD 2003/04	FYTD 2004/05	Number of Active Licenses 2002/03	Number of Active Licenses 2003/04	Number of Active Licenses 2004/05 through 6/5/05
Received							
Pharmacist (exam applications)		2082	1848	*1335	30332	31071	32161
Pharmacist (initial licensing applications)		1031	1025	*1445	n/a	n/a	n/a
Intern pharmacist		1686	1871	*1567	3962	4259	4114
Pharmacy technician		6465	7108	*5763	34961	41068	43972
Foreign educated pharmacists (evaluations)		204	359	*68	n/a	n/a	n/a
Pharmacy		390	328	288	5548	5645	5722
Sterile Compounding		n/a	96	60	0	187	225
Clinics		128	135	126	752	872	956
Hospitals		36	23	35	549	544	531
Nonresident Pharmacy		61	69	71	179	216	239
Licensed Correctional Facility		0	2	1	41	42	42
Hypodermic Needle and Syringes		27	52	26	252	275	283
Out of State Distributor		11	16	95	318	337	370
Wholesalers		165	136	77	436	477	471
Veterinary Food-Animal Drug Retailer		0	0	1	18	19	18
Exemptees		518	485	467	2625	2911	2145
Issued							
Pharmacist		1024	998	*1458			
Intern pharmacist		1403	1427	*1364			
Pharmacy technician		6077	7968	*5350			
Pharmacy		429	370	327			
Sterile Compounding		n/a	182	53			
Clinics		110	146	127			
Hospitals		39	24	39			
Nonresident Pharmacy		44	62	58			
Licensed Correctional Facility		0	2	1			
Hypodermic Needle and Syringes		30	35	37			
Out of State Distributor		72	65	71			
Wholesalers		64	86	51			
Veterinary Food-Animal Drug Retailer		0	2	2			
Exemptees		406	473	449			

*Denotes data available through 5/31/05.

Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	200	76	69	179	101	47	35	69	58	120	167	145	47
Intern pharmacist	u/a	u/a	83	u/a	u/a	66	u/a	u/a	141	u/a	u/a	64	66
Pharmacy technician	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a
Foreign educated pharmacists (evaluations)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Pharmacy	71	69	52	63	69	60	51	61	49	65	70	55	55
Sterile Compounding	43	48	50	49	49	48	48	46	60	50	52	60	60
Clinics	61	67	57	50	53	60	64	61	57	57	62	61	61
Hospitals	10	8	12	20	20	20	15	15	43	10	8	11	11
Nonresident Pharmacy	33	29	29	34	32	33	42	42	45	47	44	36	36
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypodermic Needle and Syringes	3	3	5	9	4	5	5	3	4	7	8	8	8
Out of State Distributor	47	45	50	48	43	50	59	63	71	78	80	83	83
Wholesalers	27	27	19	20	22	39	38	35	39	40	50	54	54
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	1	1	1	1	2	2	1	1
Exemtees	180	157	185	97*	92	87	80	106	95	125	143	132	132
Change of Pharmacist-in-Charge													
Received	183	229	156	151	122	111	98	91	115	127	117	112	1612
Processed	141	175	105	164	119	112	174	123	68	116	105	143	1545
Pending	214	268	319	306	309	308	232	200	247	258	270	239	239
Change of Exemptee-in-Charge													
Received	4	4	3	3	3	1	3	6	9	8	3	4	51
Processed	4	5	3	1	3	1	3	4	9	3	3	3	42
Pending	1	0	0	2	0	0	0	2	2	7	7	8	8
Change of Permits													
Received	30	86	60	61	60	44	44	81	103	101	79	60	809
Processed	24	69	49	90	61	68	41	53	60	75	102	77	769
Pending	139	156	167	138	137	113	116	144	187	213	190	173	159
Discontinuance of Business													
Received	11	15	17	18	14	13	12	18	23	5	11	14	171
Processed	0	26	0	25	1	35	0	29	12	0	12	0	140
Pending	16	21	38	31	44	22	34	23	34	39	38	52	52

Board of Pharmacy Licensing Statistics - Fiscal Year 2004/05

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	1031	3278	1249	1182	1067	1149	1170	1132	1185	1878	480		14801
Pharmacy technician	1339	3089	1763	1692	1529	1529	1608	1508	1515	1685	723		17980
Pharmacy	652	609	862	508	284	283	392	576	863	634	199		5862
Sterile Compounding	12	12	11	22	4	5	12	11	17	21	7		134
Clinics	49	149	55	50	49	53	71	57	75	74	46		728
Nonresident Pharmacy	19	32	11	18	4	20	17	10	22	21	12		186
Hypodermic Needle and Syringes	16	18	21	22	18	28	25	19	21	21	16		225
Out of State Distributor	18	56	22	23	20	20	28	13	36	39	26		301
Wholesalers	28	98	22	37	28	36	42	28	36	39	13		407
Veterinary Food-Animal Drug Retailer	1	5	1	2	0	2	0	2	2	2	0		17
Exempts	113	348	119	122	126	155	165	132	187	147	98		1712

*hand count

APPLICATIONS													
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received													
Pharmacist (exam applications)	139	109	121	109	76	88	59	45	127	172	290		1335
Pharmacist (initial licensing applications)	265	233	285	156	112	83	27	8	139	84	53		1445
Intern pharmacist	59	257	417	363	101	94	21	50	54	68	83		1567
Pharmacy technician	453	525	647	534	355	542	559	436	454	493	765		5763
Foreign educated pharmacists (evaluations)	11	57	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		68
Pharmacy	27	41	32	34	26	20	23	31	24	33	30	21	342
Sterile Compounding	4	12	4	4	4	6	5	0	8	8	5	8	68
Clinics	28	21	13	8	10	9	10	2	12	17	11	4	145
Hospitals	5	2	6	10	3	2	0	0	0	0	0	7	35
Nonresident Pharmacy	8	9	3	10	2	4	9	7	9	9	4	3	77
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	1	1
Hypodermic Needle and Syringes	2	2	5	4	0	2	1	2	2	4	2	0	26
Out of State Distributor	11	11	8	5	3	15	10	10	11	10	10	10	114
Wholesalers	8	5	6	2	9	23	7	0	6	4	15	5	90
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	1	0	0	0	1	0	0	2
Exemptees	55	29	56	40	33	18	26	43	31	55	84	28	498
Issued													
Pharmacist	307	229	226	169	129	91	34	8	160	53	52		1458
Intern pharmacist	63	178	226	274	230	73	93	38	58	50	81		1364
Pharmacy technician	672	408	663	506	353	233	670	528	468	470	379		5350
Pharmacy	28	36	49	23	20	23	32	21	25	28	25	36	346
Sterile Compounding	4	7	2	5	4	3	5	2	5	7	3	0	47
Clinics	15	15	23	15	7	7	6	5	13	20	6	5	137
Hospitals	4	2	2	2	3	2	6	0	6	0	2	4	33
Nonresident Pharmacy	4	4	3	5	4	7	0	7	8	5	7	11	65
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	0	1	1
Hypodermic Needle and Syringes	7	2	3	0	5	2	1	4	0	1	1	0	26
Out of State Distributor	4	13	8	7	8	14	1	6	1	3	8	7	80
Wholesalers	6	5	14	1	7	6	8	3	3	3	5	1	62
Veterinary Food-Animal Drug Retailer	0	3	0	0	0	0	0	0	0	0	0	1	4
Exemptees	42	52	28	45	38	26	33	17	42	25	66	39	453

ATTACHMENT G

Memorandum

To: Board Members

Date: July 8, 2005

From: Virginia Herold
Board of Pharmacy

Subject: Competency Committee Report

The board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. This committee develops and oversees administration of the California Pharmacist Jurisprudence Examination (CPJE).

Twelve individuals have been selected to participate on the committee as committee members or item writers. Orientation of these new individuals will occur this summer. The new two-tier structure for the CPJE should be in place by October 2005. Additional members for the committee have been sought from the two new schools of pharmacy.

Release of Exam Scores

The Board of Pharmacy is currently performing quality assurance assessments to ensure the appropriateness of the California Pharmacist Jurisprudence Examination (CPJE). The board initiated such a study on May 16, 2005. To assure the thoroughness of this assessment, 400 individuals will be needed for participation. Once 400 people have taken the CPJE, release of examination scores should resume on a weekly basis, usually within 14 days of the time a candidate takes the examination. Based on the number of candidates who took the CPJE last year during this same period, this will likely be early July 2005.

Annual Meeting

The Competency Committee will meet on August 18 and 19, 2005, for its annual meeting. The purpose of the annual meeting is to focus on long-term goals of the committee as well as to review the examination process to make improvements. The committee will also review the results of the job analysis survey to develop a new content outline. The committee will also develop questions for the item bank.

Job Analysis

The results of the job analysis surveys will be used to develop a content outline for future CPJE examinations. The new content outline will be developed by the committee in early 2005 and will be used in Spring 2005 to construct the CPJE.

ATTACHMENT H

Licensing Committee

2004-2005

Final Quarter Report

April 1, 2005 – June 30, 2005

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2005.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks: **1. Review 100 percent of all applications within 7 working days of receipt.**

Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				Average Days to Process:			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	369	273	231*	462**	23	24	14	7.2
Pharmacist (initial licensing)	783	351	174*	137**	3	7	3.6	5.9
Pharmacy Intern	733	558	125*	151**	10	7	10	10
Pharmacy Technicians	1625	1431	1449*	1258**	5-10	15-20	15-20	15-20
Foreign Graduates								
Pharmacies	100	95	78	92	6	9	9	9
Non-Resident Pharmacy	20	16	27	16	22	16	21	42
Wholesaler	19	34	13	24	39	4	11	47
Veterinary Drug Retailer	0	1	0	1	0	0	13	29
Exemptee	140	91	78	167	8	12	7	14
Out-of-State Distributor	30	23	29	30	7	18	11	50
Clinics	62	27	21	32	7	6	11	10
Hypo Needle & Syringe	9	6	4	6	1	8	9	9
Sterile Compounding	20	14	14	21	2	4	10	10

* Denotes March 2005 information has been added since the Third Quarter report.

**Denotes April and May 2005 information available at time of report development.

2. Process 100 percent of all deficiency documents within 3 working days of receipt.

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-7	5-10	5-10	5-10
Pharmacist (initial licensing)	3-7	5-10	5-7	5-7
Pharmacy Intern	10	7	7	7
Pharmacy Technicians	5-7	7	7	7
Foreign Graduates	N/A	N/A	N/A	N/A
Pharmacies	9	3	3	5
Non-Resident Pharmacy	10	1	0	10
Wholesaler	9	8	3	30
Veterinary Drug Retailer	0	0	1	26
Exemptee	3	4	3	2
Out-of-State Distributor	11	10	2	2
Clinics	7	2	2	1
Hypo Needle & Syringe	5	1	1	2

3. Make a licensing decision within 3 working days after all deficiencies are corrected.

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-2	1-2	1-2	1-2
Pharmacist (initial licensing)	1-2	1-2	1-2	1-2
Pharmacy Intern	5	3-5	3-5	3-5
Pharmacy Technicians	5	5	5	5
Pharmacies	4	2	1	1
Non-Resident Pharmacy	3	1	2	6
Wholesaler	3	3	1	11
Veterinary Drug Retailer	0	0	13	1
Exemptee	2	12	10	3
Out-of-State Distributor	4	3	17	7
Clinics	4	1	1	2
Hypo Needle & Syringe	6	1	5	5

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Q1	Q2	Q3	Q4
Pharmacist	762	389	202*	105**
Pharmacy Intern	467	577	189*	131**
Pharmacy Technician	1743	1092	1666*	849**
Foreign Graduate	N/A	N/A	N/A	N/A
Pharmacies	121	79	99	96
Non-Resident Pharmacy	11	10	15	23
Wholesaler	25	14	13	9
Veterinary Drug Retailer	3	0	0	1
Exemptee	122	106	92	130
Out-of-State Distributor	25	23	8	18
Clinics	53	24	24	31
Hypo Needle & Syringe	12	6	5	2
Sterile Compounding	13	16	10	10

* Denotes March 2005 information has been added since the Third Quarter report.

** Denotes April and May 2005 information available at time of report development.

5. Withdrawn licenses to applicants not meeting board requirements.

	Q1	Q2	Q3	Q4
Pharmacy Technician	11	0	10	8
Pharmacies	15	1	1	3
Non-Resident Pharmacy	13	1	7	1
Clinics	28	3	11	3
Sterile Compounding	2	5	0	0
Exempteas	0	32	8	18
Hypo Needle & Syringe	0	3	2	2
Out-of-State Distributor	0	8	9	7
Wholesaler	0	4	4	1

Objective 2.2: Implement at least 50 changes to improve licensing decisions by June 30, 2005.

Measure: Number of implemented changes.

Tasks: 1. Review Pharmacist Intern Program.

9/04 Governor signed SB 1913 that contained new intern provisions to become effective 1/05.

- 9/04 Licensing Committee recommended changes to 1728 to implement SB 1913.*
- 9/04 Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*
- 9/04 Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*
- 12/04 Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

2. Implement changes to the Pharmacy Technician Program.

- 1/04 a. Use PTCB as a qualifying method for registration. – Completed.*
- 1/04 b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*
- 9/04 c. Eliminate clerk-typist from pharmacist supervisory ratio.
Completed – regulation approved by OAL, change effective 10/3/04.*
- 9/04 Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*
- 10/04 Board approved the recommendation and will sponsor legislation in 2005.*
- 3/05 SB 1111 (B&P Committee) was introduced.*

3. Administer a pharmacist licensure exam more than twice a year.

- 3/04 Completed – CA applications began taking the NAPLEX and CPJE.*
- 9/04 826 California applicants have taken the NAPLEX and 1,006 have taken the CPJE since July 1, 2004.*
- 1/05 1,240 California applicants have taken the NAPLEX and 1,335 have taken the CPJE since July 1, 2004.*
- 4/05 1,450 California applicants have taken the NAPLEX and 1,648 have taken the CPJE since July 1, 2004.*
- 7/05 1,670 California applicants have taken the NAPLEX and 1,804 have taken the CPJE since July 1, 2004.*

4. **Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.**
5. **Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.**
6. **Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.**

8/04 Competency Committee met for two days and developed questions as well as the job analysis.

9/04 Competency Committee met for two days and developed questions.

9/04 Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).

10/04 Competency Committee met for two days and developed questions.

11/04 Job analysis will be released.

12/04 Job analysis released to 3,000 pharmacists.

1/05 Competency Committee met for two days and developed questions.

2/05 Competency Committee met for two days and developed questions.

4/05 Competency Committee met for two days and developed questions.

7. **Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.**

6/04 Completed

9/04 OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.

9/04 Reported that 13 sterile compounding licenses have been issued since July 1, 2004.

1/05 Reported that 29 sterile compounding licenses have been issued since July 1, 2004.

8. Issue temporary permits whenever change of ownership occurs.

9/04 1st Quarter – 22 temporary permits issued.

1/05 2nd Quarter – 29 temporary permits issued.

4/05 3rd Quarter – 29 temporary permits issued.

7/05 4th Quarter – 26 temporary permits issued.

9. Establish means for licensee to renew permits on line.

8/04 Submitted Applicant Tracking System (ATS) report to the department.

11/04 Met with the department to discuss conversion to ATS and department prioritization.

10. Implement Changes to Facilities Licensure Requirements

9/04 Governor signed SB 1913 that included application requirements for all applicants.

9/04 Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.

9/04 Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.

1/05 New application forms are available for nonresident wholesalers.

1/05 New application forms are available for wholesalers.

2/05 Initiate review of clinic application requirements.

3/05 Initiate review of community pharmacy application requirements.

3/05 Initiate implementation of the surety bond requirement.

6/05 Submitted proposed change to clinic application requirement.

11. Review the Ownership of Pharmacies

7/04 Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

7/04 Draft report provided to the board.

- 9/04 Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).
- 9/04 Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.
- 12/04 Report provided to the Legislature.

13. Evaluate application requirements for all licenses.

- 9/04 Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.
- 9/04 Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).
- 9/04 Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.
- 9/04 Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.
- 9/04 Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.
- 9/04 Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.
- 10/04 Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.
- 12/04 Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.
- 3/05 SB 1111 (B&P) introduced that contains statutory changes to eliminate "Rules of Professional Conduct."

14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.

- 9/04 Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.

- 9/04** *Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*
- 9/04** *Sent a letter to all pending foreign graduates advising of law change and suspending application process.*
- 12/04** *Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*

15. Review the law regarding continuing education (CE) requirements for pharmacists.

- 7/04** *Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*
- 9/04** *Licensing Committee recommended changes to the CE statute to relocate from regulation the 30-hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*
- 9/04** *Licensing Committee recommended revisions to the CE regulations.*
- 10/04** *Board approved recommended statutory and regulatory revisions to CE requirements.*
- 1/05** *SB 1111 (B&P) introduced that contains CE provision.*
- 6/05** *Reviewed the Pharmacist Self-Assessment Mechanism (PSAM) available from the National Association of Boards of Pharmacy (NABP) and determine options for pharmacists to obtain CE for completing the assessment. Determined what other competency assessments that available.*

16. Review the license of city and county jails and juvenile facilities.

- 8/04** *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

17. Review the certification process for foreign graduates that was implemented 1/05 and the Test of Spoken English (TSE requirement).

- 3/05** *Licensing Committee discussed the certification process and TSE requirement. Requested TSE presentation at future board meeting.*

Objective 2.3:	Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.
Measure:	Number of public policy initiatives evaluated.
Tasks:	<p data-bbox="451 346 1230 377">1. Explore the need to regulate pharmacy benefit managers.</p> <p data-bbox="357 410 975 441"><i>10/03 Board concluded not to regulate PBMs.</i></p> <p data-bbox="357 476 1355 540"><i>9/04 Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.</i></p> <p data-bbox="357 576 1334 640"><i>1/05 AB 78 introduced to define PMBs and require specified disclosures to purchases.</i></p> <p data-bbox="451 675 1374 706">2. Explore the need to regulate drugs labeled for “veterinary use only.”</p> <p data-bbox="357 741 1299 772"><i>9/03 SB 175 was introduced and signed (Chaptered 250, Statutes 2003).</i></p> <p data-bbox="357 808 644 839"><i>1/04 Completed.</i></p> <p data-bbox="451 874 1225 905">3. Explore the importation of drugs from foreign countries.</p> <p data-bbox="357 940 903 971"><i>7/04 Discussed at July Board meeting.</i></p> <p data-bbox="357 1006 1190 1038"><i>9/04 Discussed at September Enforcement Committee meeting.</i></p> <p data-bbox="357 1073 1401 1137"><i>9/04 Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.</i></p> <p data-bbox="357 1172 948 1203"><i>10/04 Discussed at October board meeting.</i></p> <p data-bbox="357 1239 1187 1270"><i>12/04 Discussed at December Enforcement Committee meeting.</i></p> <p data-bbox="357 1305 1267 1336"><i>12/04 HHS released its report of the Task Force on Drug Importation.</i></p> <p data-bbox="357 1371 948 1402"><i>1/05 Discussed at January board meeting.</i></p> <p data-bbox="357 1437 1150 1469"><i>3/05 Discussed at March Enforcement Committee Meeting.</i></p> <p data-bbox="357 1504 916 1535"><i>4/05 Discussed at April board meeting.</i></p> <p data-bbox="357 1570 1126 1601"><i>6/05 Discussed at June Enforcement Committee Meeting.</i></p>

4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.

9/04 OAL approved regulation change and will take effect 10/22.

10/04 Completed.

5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding

9/04 Held third meeting of workgroup on compounding – proposed draft concept on general compounding.

12/04 Held fourth meeting of workgroup on compounding – recommending statutory proposal.

12/04 Licensing Committee recommended approval of statutory proposal to define general compounding and regulatory parameters.

1/05 Board approved general compounding proposal.

2//05 AB 595 was introduced and sponsored by the board.

6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)

7/04 Protocol on Web site.

7/04 Board approved regulation on protocol.

9/04 Regulation submitted to OAL for approval.

11/04 OAL approved regulation, which became effective 12/04.

7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.

9/04 *Governor signed SB 1913 that provides authority.*

8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.

4/04 *Board approved waiver for two years.*

9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.

12/04 *Licensing Committee discussed concepts related to proposal.*

3/05 *Licensing Committee discussed draft and proposal.*

Objective 2.4:	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.
Measure:	Percentage of cashiered application and renewal fees within 2 working days.
Tasks:	<p>1. Cashier application fees.</p> <p><i>9/04 1st Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p> <p><i>1/05 2nd Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p> <p><i>4/05 3rd Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p> <p><i>7/05 4th Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p> <p>2. Cashier renewal fees.</p> <p><i>9/03 The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.</i></p> <p><i>8/04 Held interviews for renewal cashier because hiring freeze was lifted.</i></p> <p><i>9/04 1st Quarter - Average processing time for central cashiering is 2-3 weeks.</i></p> <p><i>10/04 Filled vacancy for renewal cashier.</i></p> <p><i>1/05 2nd Quarter – Average processing time for central cashiering is 1-2 weeks.</i></p> <p><i>4/05 3rd Quarter – Average processing time for central cashiering is 1-2 weeks.</i></p> <p><i>7/05 4th Quarter – Average processing time for central cashiering is 1-2 weeks.</i></p>
Objective 2.5:	Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.
Measure:	Percentage response for verifying licensing information within 5 working days.
Tasks:	<p>1. Respond to requests for licensing verification.</p> <p><i>9/04 1st Quarter – Processed 227 license verifications.</i></p> <p><i>1/05 2nd Quarter – Processed 208 license verifications.</i></p>

4/05	3 rd Quarter – Processed 198 license verifications.
7/05	4 th Quarter – Processed 301 license verifications.
Objective 2.6: Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.	
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	<p>1. Make address and name changes.</p> <p>9/04 1st Quarter – Processed 2,478 address changes.</p> <p>1/05 2nd Quarter – Processed 1, 557 address changes.</p> <p>4/05 3rd Quarter – Processed 1,848 address changes.</p> <p>7/05 4th Quarter – Processed 1,441 address changes.</p> <p>2. Process discontinuance of businesses forms and related components.</p> <p>9/04 1st Quarter – Processed 26 discontinuance- of-business forms. Processing time is 44 days.</p> <p>1/05 2nd Quarter – Processed 61 discontinuance- of-business forms. Processing time is 40 days.</p> <p>4/05 3rd Quarter – Processed 44 discontinuance- of-business forms. Processing time is 19 days.</p> <p>7/05 4th Quarter – Processed 12 discontinuance- of-business forms. Processing time is 30 days.</p> <p>3. Process changes in pharmacist-in-charge and exemptee-in-charge.</p> <p>9/04 1st Quarter – Processed 421 pharmacist-in-charge changes. Average processing time is 23 days. Processed 12 exemptee-in-charge changes. The average processing time is 2 days.</p> <p>1/05 2nd Quarter – Processed 395 pharmacist-in-charge changes. Average processing time is 25 days. Processed 6 exemptee-in-charge changes. The average processing time is 2 days.</p> <p>4/05 3rd Quarter – Processed 365 pharmacist-in-charge changes. Average processing time is 15 days. Processed 16 exemptee-in-charge changes. The average processing time is 5 days.</p> <p>7/05 4th Quarter – Processed 364 pharmacist-in-charge changes. Average processing time is 14 days. Processed 9 exemptee-in-charge changes. The average processing time is 7 days.</p>

4. Process off-site storage applications.

9/04 *Processed 33 off-site storage applications.*

1/05 *Processed 15 off-site storage applications.*

4/05 *Processed 20 off-site storage applications.*

7/05 *Processed 20 off-site storage applications.*

5. Process change-of-permit applications.

9/04 *1st Quarter – Processed 142 applications. Average processing time is 25 days.*

1/05 *2nd Quarter – Processed 219 applications. Average processing time is 15 days.*

4/05 *3rd Quarter – Processed 169 applications. Average processing time is 19 days.*

7/05 *4th Quarter – Processed 254 applications. Average processing time is 10 days.*